



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; comment request (60-Day FRN): The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To submit comments in writing, request more information on the proposed

project, or to obtain a copy of the data collection plans and instruments, contact: Jane Hoppin, Sc.D., Epidemiology Branch, National Institute of Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, PO Box 12233, MD A3-05, Research Triangle Park, NC 27709, or call non-toll-free number 919-541-7622, or e-mail your request, including your address to: hoppin1@niehs.nih.gov.

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture, 0925-0406, Expiration Date 5/31/2013 – REVISION - National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this information collection is to continue and complete updating the occupational and environmental exposure information as well as medical history information for licensed pesticide applicators and their spouses enrolled in the Agricultural Health Study. This represents a request to complete phase IV (2013-2015) of the study and to continue and complete the buccal cell collection and the Study of Biomarkers of Exposures and Effects in Agriculture (BEEA). The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. The phase IV follow up data will be collected by using one of three methods of the cohort member's choosing: self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer

administered computer assisted telephone interview (CATI). Proxy interviews for those cohort members unable to complete the follow up will be completed by using one of the three methods as well. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer.

Questionnaire data will be collected by using computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents will also be asked to participate in the collection of biospecimens including blood, urine, and buccal cells (loose cells from the respondent's mouth). The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 10,465.

Estimated Annualized Burden Hours

Table A.12-1 ESTIMATES ANNUALIZED BURDEN HOURS					
Type of Respondent	Form	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hour
Private and Commercial Applicators and Spouses	Reminder, Missing, and Damaged Scripts for Buccal Cell	100	1	5/60	8
Private Applicators	BEEA CATI Screener	480	1	20/60	160
Private Applicators	BEEA Home Visit CAPI, Blood, & Urine x 1	160	1	30/60	80
Private Applicators	BEEA Schedule Home Visit Script	20	3	5/60	5
Private Applicators	BEEA Home Visit CAPI, Blood, & Urine x 3	20	3	30/60	30
Private Applicators	Paper/pen, CAWI or CATI	13,855	1	25/60	5,773
Spouses	Paper/pen, CAWI or CATI	10,201	1	25/60	4,250
Proxy	Paper/pen, CAWI or CATI	635	1	15/60	159
Total					10,465

Dated: November 30, 2012

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[FR Doc. 2012-29548 Filed 12/05/2012 at 8:45 am; Publication Date: 12/06/2012]